In the United States Court of Federal Claims

No. 09-39 V
Filed: September 8, 2014*
TO BE PUBLISHED

AMY CRUTCHFIELD, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-10 *et seq.* (2012); MMR vaccine; Diabetes Type 1.

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MEMORANDUM OPINION AND FINAL ORDER

BRADEN, *Judge*.

Amy Crutchfield ("Petitioner") claims entitlement to compensation under the National Childhood Vaccine Injury Act of 1986, codified as amended at 42 U.S.C. § 300aa-10 *et seq.* (2012) (the "Vaccine Act"), because she developed Type 1 diabetes mellitus ("Type 1 diabetes") following a measles-mumps-rubella ("MMR") vaccination.

* Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims ("VRCFC"), this Memorandum Opinion and Final Order was filed under seal on August 22, 2014 and "held for 14 days to afford each party the opportunity to object to the public disclosure of any information furnished by that party." VRCFC 18(b).

On April 7, 2014, Special Master George L. Hastings, Jr. (the "special master") denied Petitioner's claim for compensation, finding that she failed to satisfy the three elements set forth by the United States Court of Appeals for the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *See Crutchfield v. Sec'y of Health & Human Servs.*, No. 09-39, 2014 WL 1665227, at *21–22 (Fed. Cl. Apr. 7, 2014).

On April 29, 2014, Petitioner filed a Motion for Review of the special master's Decision.

I. RELEVANT FACTS.[1]

A. Petitioner's Medical Records.

Petitioner was born on October 17, 1970 in Manhasset, New York. Pet. 1/16/09 Ex. 7 at 118. On October 18, 1971, she received the live measles vaccine. Pet. 1/16/09 Ex. 7 at 119. On April 21, 1972, she received the mumps vaccine. Pet. 1/16/09 Ex. 7 at 119. On January 31, 1972, she received the rubella live virus vaccine. Pet. 1/16/09 Ex. 7 at 119. On May 24, 1978, she received the measles vaccine booster. Pet. 1/16/09 Ex. 7 at 119.

As an adult, Petitioner's blood glucose periodically was tested as part of her routine health care. Pet. 1/16/09 Ex. 6 at 93–116. On February 8, 2002, her blood glucose levels were found to be normal, and slightly low on August 14, 2003, at 63 mg/dL compared to a reference range of 70–105 mg/dL. Pet. 1/16/09 Ex. 6 at 102, 113. On May 16, 2005, before she began experiencing the health problems at issue in this case, a blood glucose test was taken and the results were normal. Pet. 1/16/09 Ex. 6 at 98.

On October 19, 2005, Dr. Orli Etingin, an internist, reported that Petitioner was trying to conceive. Pet. 1/16/09 Ex. 6 at 93. On December 15, 2005, Petitioner visited her gynecologist, Dr. Julie Beyers, for a "routine exam" with the "chief . . . reason for visit" that she was "attempting conception[.]" This exam included a laboratory blood test; the results indicated that Petitioner was not immune to measles, had an "equivocal" immune response to mumps, but was immune to rubella. Pet. 1/16/09 Ex. 2 at 6, 9. A follow up test on January 6, 2006, had the same results. Pet. 1/16/09 Ex. 2 at 11.

Petitioner did not experience any serious health problems before 2006. Pet. 1/16/09 Ex. 6 at 93–116. On or around January 26, 2006, Petitioner received a MMR vaccination.[2]

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[1] The relevant facts cited herein primarily were derived from the January 16, 2009 Petition, as well as the exhibits submitted by both Petitioner and the Government. As the special master noted, however, both parties occasionally assigned the same exhibit number to more than one document in the record, and did not always sequentially number exhibits. *Crutchfield*, 2014 WL 1665227, at *3 n.4. Therefore, to avoid confusion, this Opinion will include the date of filing when referencing exhibits. Medical articles will be referred to as "Art." and other exhibits as "Ex." Otherwise, references to exhibits will retain the lettering or numbering used by the parties.

[2] A July 23, 2008 letter from Aetna, in response to Ms. Crutchfield's "request for information" reported that Petitioner received the MMR vaccine on January 26, 2006. Pet.

During April and May 2006, Petitioner experienced recurrent vaginal yeast infections and, on April 4, 2006, Dr. Beyers prescribed treatment with Diflucan. Pet. 1/16/09 Ex. 2 at 10, 13, 16. Laboratory tests performed on May 5, 2006 showed no urogenital infection. Pet. 1/16/09 Ex. 2 at 18. On May 30, 2006, Dr. Beyers began treating Petitioner with Clomid to promote fertility. Pet. 1/16/09 Ex. 2 at 18. On June 19, 2006, Petitioner visited Dr. Etingin and reported that over the past three to four months, she experienced hair loss, increased thirst, and unintentional weight loss, despite a decrease in exercise. Pet. 1/16/09 Ex. 6 at 90. During this visit, Petitioner requested that blood tests be performed, because she suspected Type 1 diabetes. Pet. ¶¶ 8, 9. The results confirmed that Petitioner was suffering from diabetes. Pet. 1/16/09 Ex. 5 at 29, 71–74.

On June 23, 2006, Dr. Levy, an endocrinologist, saw Petitioner, whose family history included rheumatoid arthritis in her mother and aunt and celiac disease in a maternal cousin, but no history of diabetes mellitus. Pet. 1/16/09 Ex. 5 at 33.[3] Nevertheless, Dr. Levy diagnosed Petitioner with Type 1 diabetes. Pet. 1/16/09 Ex. 5 at 34; Pet. 1/16/09 Ex. 6 at 79. Thereafter, Petitioner began a program of insulin treatment and, on July 5, 2006, Dr. Levy reported that Petitioner's blood glucose levels improved. Pet. 1/16/09 Ex. 5 at 31, 35. In February 2007, Dr. Levy prescribed an insulin pump for Petitioner. Pet. 1/16/09 Ex. 5 at 24.

On January 31, 2011, blood tests were requested by the Government's expert, Dr. Noel Mclaren, and the results confirmed that Petitioner had Type 1 diabetes. Pet. 2/9/11 Exs. 101, 102.

B. Type 1 Diabetes Mellitus.

Type 1 diabetes is an autoimmune disease, where the patient's immune system attacks and destroys islet cells (also referred to as "beta cells") in the patient's pancreas. Pet. 1/16/09 Ex. 1 at 4; Gov't 5/8/09 Ex. A at 3; *Crutchfield*, 2014 WL 1665227, at *8. The resulting damage to the pancreas requires the patient to take insulin to survive. Pet. Ex. 1/16/09 Ex. 1 at 4; *Crutchfield*, 2014 WL 1665227, at *8.

1/16/09 Ex. 4 at 19. The Government's expert witness, Dr. Barry Bercu, agreed. Gov't 5/8/09 Ex. A at 2. The Government's May 8, 2009 Report, however, states that "January 24, 2006 was confirmed [as the date of vaccination] by insurance." Gov't 5/8/09 Ex. A at 3. Petitioner's primary care records, however, report the date of vaccination as "11/24/06," on a document dated January 26, 2006. Pet. 1/16/09 Ex. 4 at 1. Given these conflicting sources, the special master cited January 26, 2006 as the vaccination date, but stated that "the exact date . . . is not relevant—it is relevant only that [Petitioner] definitely received a MMR vaccination on or about January 26, 2006." *Crutchfield*, 2014 WL 1665227, at *4 n.6.

[3] The special master acknowledged that the medical record in this case is "not easily legible," but noted that Dr. Shoenfeld, for Petitioner (Pet. 1/16/09 Ex. 1 at 2) and Dr. Bercu, for the Government (Gov't 5/8/09 Ex. A at 2) both agree on the family history presented here. *Crutchfield*, 2014 WL 1665227, at *4 n.6.

First identified in children, more recently Type 1 diabetes also has been found in adults, which is sometimes referred to as "latent autoimmune diabetes in adulthood," or "LADA." Gov't 5/8/09 Ex. A at 3; *Crutchfield*, 2014 WL 1665227, at *8. Although causation of this condition is not well understood, experts agree that genetic susceptibility to autoimmune disease and environmental factors may play a role. Gov't 5/8/09 Ex. A at 6–7; Pl. 1/16/09 Ex. 1 at 4; *Crutchfield*, 2014 WL 1665227, at *9.

C. Petitioner's Expert Testimony.

1. Yehuda Shoenfeld, M.D.[4]

In 1972, Dr. Yehuda Shoenfeld received his medical degree from the Hebrew University's Hadassa Medical School in Israel. He is a Professor of Medicine at the Tel-Aviv University Medical School, Sackler Faculty of Medicine, and served as the head of the Department of Medicine at the Sheba Medical Center of Tel-Aviv University, the largest hospital in Israel. He also has served as the head of the Hybridoma Unit and Research Laboratory for Autoimmune Diseases of the Soroku Medical Center of Ben-Gurion University of the Negev, and, in that capacity, founded the Center for Autoimmune Diseases, where he serves as Director. Dr. Shoenfeld has authored or co-authored over 1,200 articles, 43 books, and 130 chapters in medical texts, many of them focusing on autoimmune diseases. He is the Editor-in-Chief of *Autoimmunity Reviews*, Co-Editor of the *Journal of Autoimmunity*, and has served on the Editorial Boards of numerous other medical journals. As head of the Department of Medicine at the Sheba Medical Center, he has treated many types of patients, approximately 15 to 20 percent of whom are diabetic.

Dr. Shoenfeld noted that Type 1 diabetes is an autoimmune condition and that Petitioner's family history of autoimmune conditions made her more susceptible. 3/30/11 TR 22, 59, 66 (Shoenfeld). He theorized that the MMR vaccine could have triggered the rapid onset of Type 1 diabetes through a process called "molecular mimicry." In this process, the body's immune system mistakenly attacks parts of the body that have similar molecular structures to invasive agents. In this case, Petitioner's immune system may have experienced a molecular similarity between the islet cells on her pancreas and components of the MMR vaccine. Pet. 1/16/09 Ex. 1 at 7–8; Pet. 10/27/12 Ex. 84 at 3; 3/30/11 TR 48–49 (Shoenfeld). As support, Dr. Shoenfeld referenced medical literature indicating that the wild mumps virus can trigger diabetes so the mumps vaccine also could trigger the same response. Pet. 1/16/09 Ex. 1 at 4–7; 3/30/11 TR 28–33 (Shoenfeld). He also stated that Type 1 diabetes is unique in that some infections and vaccines have been shown to prevent the disease, while others are shown to cause it, which may explain why this association has not been observed in large epidemiological studies. Pet. 1/16/09 Ex. 1 at 9.

Dr. Shoenfeld opined that because Petitioner previously received the MMR vaccination as a child, the rapid destruction of islet cells and correspondingly quick onset of symptoms of

[4] Dr. Shoenfeld's credentials were cited in his *curriculum vitae* (Pet. 1/16/09 Ex. 1) and trial testimony. 3/30/11 TR 4–20 (Schoenfeld); *see also Crutchfield*, 2014 WL 1665227, at *6–7 (reciting Dr. Shoenfeld's qualifications).

Type 1 diabetes could be explained by an "anamnestic response." 3/30/11 TR 93 (Schoenfield). This is a secondary response, where the immune system responds quickly and violently to an antigen that it has encountered before. 3/30/11 TR 93–94 (Shoenfeld). Since Petitioner showed no symptoms of diabetes prior to the vaccination, the rapid onset must have been caused by a trigger such as the vaccine. 3/30/11 TR 24–26 (Shoenfeld).

D. The Government's Expert Testimony.

1. Barry B. Bercu, M.D.[5]

In 1969, Dr. Bercu was awarded a medical degree from the University of Maryland. From 1970 to 1972, he was a resident in pediatrics at the Massachusetts General Hospital in Boston before serving as a pediatrician in the United States Air Force until 1974. Thereafter, Br. Bercu served as a research fellow in pediatric endocrinology and metabolism at Massachusetts General Hospital and a research fellow in endocrinology at Tufts University Medical School in Boston, from 1974 to 1977. In 1972, he received board certification in pediatrics, and in 1978, pediatric endocrinology.

In 1974, Dr. Bercu became a Senior Surgeon in the United States Public Health Service, and beginning in 1977, held a series of positions at the National Institutes of Health focusing on children's health. From 1984 to the present, Dr. Bercu has been a Professor at the University of South Florida College of Medicine. He also maintains a clinical practice at the Tampa General Hospital and the Shriner's Hospital of Tampa. He has published more than 170 medical journal articles, mostly focused on endocrine disorders.

Dr. Bercu testified that there is no relationship between Petitioner's Type 1 diabetes and the MMR vaccine, because diabetes requires years to develop and Petitioner's vaccine was administered only months prior to her symptoms. 3/30/11 TR 163–64 (Bercu).

2. Noel Maclaren, M.D.[6]

In 1963, the University of Otago, in New Zealand, awarded Dr. Noel Maclaren a medical degree. Between 1963 and 1968, he specialized in Medicine and Pediatrics at the Wellington Hospital in New Zealand. In 1969, Dr. Maclaren was a Senior Resident at the Queen Elizabeth Hospital for Sick Children, in London. He then served as a Fellow and Associate Professor at the University of Maryland School of Medicine, from 1972 to 1978, focusing on pediatrics, endocrinology, and metabolism. Dr. Maclaren received pediatric board certification in 1976 and a certification in pediatric endocrinology in 1978.

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[5] Dr. Bercu's credentials were cited in his *curriculum vitae* (Gov't 5/8/09 Ex. B) and his testimony at trial. 3/30/11 TR 161–63 (Bercu); *see also Crutchfield*, 2014 WL 1665227, at *7 (reciting Dr. Bercu's qualifications).

[6] Dr. Maclaren's credentials were cited in his *curriculum vitae* (Gov't 4/1/10 Ex. E) and his testimony at trial. 3/30/11 TR 107–18 (Maclaren); *see also Crutchfield*, 2014 WL 1665227, at *8 (reciting Dr. Maclaren's qualifications).

In 1978, Dr. Maclaren joined the College of Medicine of the University of Florida as a Professor of Pathology and Pediatrics. In 1997, the Louisiana State University College of Medicine appointed him Professor of Pediatrics and, in the following year, he became a Professor of Biometry and Genetics, while also serving as the Director of the Research Institute for Children at the Children's Hospital of New Orleans. In 1999, he began a five-year service at the Weill College of Medicine at Cornell University, while also directing the Cornell Juvenile Diabetes Program. From 2004 to the present, Dr. Maclaren has been a Professor of Pediatrics at the Weill-Cornell College of Medicine and New York Hospital. He has authored or co-authored over 200 medical journal articles and over 80 books or book chapters, mostly on the subject of endocrinology and Type 1 diabetes.

Dr. Maclaren testified that recent studies have found no causal relationship between any vaccine and Type 1 diabetes. 3/30/11 TR 112–13, 120, 132, 191 (Maclaren). Dr. Maclaren opined that the disease evolves slowly in adults, over many years, and thus symptoms indicating the destruction of islet cells, as seen in Petitioner, could not have been caused by a vaccine taken only a few months prior. 3/30/11 TR 118, 129, 131–32, 139–40, 152 (Maclaren).

II. PROCEDURAL HISTORY.

On January 16, 2009, Petitioner filed a Petition for compensation in the United States Court of Federal Claims, together with the expert report of Dr. Yehuda Shoenfeld (Pet. 1/16/09 Ex. 1) and Petitioner's medical records (Pet. 1/16/09 2–7), alleging that the MMR vaccination she received on January 26, 2006 caused her to develop diabetes. Pet. ¶ 15. The case was assigned to Special Master Richard Abell. On May 8, 2009, the Government filed a Respondent's Report ("Gov't Report"), together with an expert report of Dr. Barry Bercu (Gov't 5/8/09 Ex. A), arguing that Petitioner is not entitled to compensation.

On July 6, 2009, Petitioner filed a second expert report of Dr. Shoenfeld.

On August 21, 2009, the Government filed medical articles. Gov't 8/21/09 Arts. A–OO. On September 9, 2009, the Government filed another report by Dr. Bercu. Gov't 9/9/09 Ex. C.

On October 1, 2009, Special Master Abell issued an Order allowing the parties additional time to file supplemental expert reports.

On March 29, 2010, the case was reassigned to Special Master George L. Hastings, Jr.

On April 1, 2010, the Government filed the expert report of Dr. Noel Maclaren. Gov't 4/1/10 Ex. D. On January 12, 2011, Petitioner submitted a letter from Dr. Carol Levy. Pet. 1/12/11 Ex. 100. On January 25, 2011, the Government filed the report of Dr. Maclaren. Gov't 1/25/11 Ex. F. Following Dr. Maclaren's suggestion, blood samples were drawn from Petitioner on January 31, 2011, and the results were filed with the court. Pet. 2/9/11 Exs. 101, 102.

On March 4, 2011 and March 7, 2011, respectively, the Government and Petitioner filed Pre-Hearing Memoranda. On March 30, 2011, an evidentiary hearing was conducted, wherein Special Master Hastings heard the testimony of Petitioner's expert Dr. Shoenfeld, and the Government's experts, Drs. Maclaren and Bercu. 3/30/11 TR 1–201. At that time, Petitioner also introduced other medical articles, later filed with the court on May 12, 2011. Pet. 5/12/11

Arts. 70–80. On July 18, 2011, the Government filed the Supplemental Report of Dr. Maclaren. Gov't 7/18/11 Ex. G. On August 4, 2011, the Government filed additional medical articles. Gov't 8/4/11 Arts. H–T.

On August 31, 2011 and October 31, 2011, respectively, Petitioner and the Government filed Post-Hearing Memoranda. The Government's Post-Hearing Memorandum noted that a new study by the Institute of Medicine ("IOM Report") became available after the evidentiary hearing and was highly relevant to the case. On January 31, 2012, the Government filed a motion to introduce the IOM Report, including the relevant section as an exhibit. Gov't 1/31/12 Art. NNN. On February 13, 2012, Petitioner objected to the submission of the IOM Report. On May 14, 2012, Special Master Hastings admitted the IOM Report as part of the evidentiary record. On October 27, 2012, however, Petitioner was allowed to file another report by Dr. Shoenfeld in response to the IOM Report. Pet. 10/27/12 Ex. 84. And, on April 18, 2013, Petitioner filed a Reply to the Government's Post-Hearing Memorandum.

On April 7, 2014, Special Master Hastings issued a Decision denying Petitioner compensation. *See Crutchfield*, 2014 WL 1665227. On April 29, 2014, Petitioner filed a timely Motion For Review. On May 29, 2014, the Government filed a Response.

III. DISCUSSION.

A. Jurisdiction And Standard Of Review.

The National Childhood Vaccine Injury Act of 1986 displaced most state common law tort actions against vaccine manufacturers. *See* Pub. L. No. 99-660 tit. II, 100 Stat. 3743 (codified at 42 U.S.C. § 201, 300aa *et seq.*); *see also Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1072–74 (2011) (describing the history of the Vaccine Act). Under the original 1986 Vaccine Act, United States District Courts had jurisdiction to determine if a petitioner was entitled to compensation, and would review a special master's proposed findings of fact or conclusions of law *de novo*. *See* Pub. L. No. 99-660, § 2112(a), (d), 100 Stat. at 3761–62.

The Vaccine Compensation Amendments of 1987 transferred jurisdiction over vaccine injury petitions to the United States Claims Court.[7] Pub. L. No. 100-203, § 4307, 101 Stat. 1330, 1330-224 to 1330-225 (amending 42 U.S.C. § 300aa-11). Thereafter, the Omnibus Budget Reconciliation Act of 1989 established, within the United States Claims Court, an office of special masters to review compensation claims, under the 1986 Vaccine Injury Act. *See* Pub. L. No. 101-239, § 6601(e), 103 Stat. 2106, 2286–89 (amending 42 U.S.C. § 300aa-12). In addition, the standard of review was changed. Instead of *de novo* review, the United States Claims Court was directed by Congress to "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." Pub. L. No. 101-239, § 6601(h), 103 Stat. at 2289–90 (codified at 42 U.S.C. § 300aa-12(e)(2)(B)). In sum, if a special

[7] In 1992, Congress replaced references to the "United States Claims Court" with the "United States Court of Federal Claims." *See* Federal Courts Administration Act of 1992, Pub. L. No. 102-572, § 902, 106 Stat. 4506.

master has considered the relevant evidence of record, drawn plausible inferences, and articulated a rational basis for the decision, 'reversible error will be extremely difficult to demonstrate.'" (quoting *Hazlehurst v. Sec'y of Health & Human Servs.*, 604 F.3d 1343, 1349 (Fed. Cir. 2010))).

Accordingly, the United States Court of Appeals for the Federal Circuit has held that the United States Court of Federal Claims may conduct only a limited review of the decisions of a special master under the Vaccine Act. *See Markovich v. Sec'y of Health & Human Servs.*, 477 F.3d 1353, 1355–56 (Fed. Cir. 2007) (citing 42 U.S.C. § 300aa-12(e)(2)(B)) ("Under the Vaccine Act, the Court of Federal Claims reviews the special master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'"). "Each standard applies to a different aspect of the judgment." *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). Findings of fact by a special master are reviewed under the "arbitrary and capricious" standard. *See Masias v. Sec'y of Health & Human Servs.*, 634 F.3d 1283, 1287 (Fed. Cir. 2011). The "arbitrary and capricious" standard is a "highly deferential standard of review. [So,] [i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see also Munn*, 970 F.2d at 870 ("['Arbitrary and capricious'] is a standard well understood to be the most deferential possible."). Evidentiary rulings, however, are reviewed under an "abuse of discretion standard." *Id.* at 870 n.10. Finally, legal issues are reviewed under the "not in accordance with the law" standard. *Id.* at 870 n.10; *see also Masias*, 634 F.3d at 1288 (citations omitted) ("'[N]ot in accordance with law' refers to the application of the wrong legal standard[.]"). In sum, it is not the role of a court "to reweigh the factual evidence, or to assess whether the Special Master correctly evaluated the evidence." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotations omitted); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) ("We do not reweight the factual evidence[.]").

The April 7, 2014 Petition argues that the United States Court of Federal Claims constitutionally is required to apply a *de novo* standard of review to the decision of a special master under the 1986 Vaccine Act, as amended. Pet. Mot. 4. Petitioner cites to a recent United States Supreme Court decision holding that "Congress may not 'withdraw from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty.'" Pet. 2–3 (quoting *Stern v. Marshall*, 131 S. Ct. 2594, 2609 (2011) (quoting *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1855))). The 1989 amendment to the 1986 Vaccine Act, according to Petitioner, unconstitutionally withdrew "from judicial cognizance . . . [a] matter which, from its nature, is the subject of a suit at common law[.]" Pet. Mot. 4–5 (quoting *Stern*, 131 S. Ct. at 2609). Therefore, the 1989 amendment is unconstitutional and a *de novo* standard of review must be applied by the United States Court of Federal Claims, as it was in the original 1986 Vaccine Act. Pet. Mot. 4.

The United States Court of Federal Claims is bound by congressional directives and decisions of the United States Court of Appeals for the Federal Circuit. *See Preminger v. Sec'y of Veterans Affairs*, 517 F.3d 1299, 1319 (Fed. Cir. 2008) ("*Stare decisis* in essence 'makes each judgment a statement of the law, or precedent, binding in future cases before the same court *or*

another court owing obedience to its decision[.]'" (quoting *Mendenhall v. Cedarrapids, Inc.*, 5 F.3d 1557, 1570 (Fed. Cir. 1993) (emphasis added))). Moreover, as an Article I court, *de novo* review of the special master's decision cannot resolve the constitutional question Petitioner raises. Therefore, whether the United States Court of Federal Claims is required to conduct a *de novo* review, is a legal question that our appellate court, as an Article III tribunal, may decide to resolve or not.[8] *See Lyng v. Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445-46, (1988) ("A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them. This principle required the courts below to determine, before addressing the constitutional issue, whether a decision on that question could have entitled respondents to relief beyond that to which they were entitled on their statutory claims. If no additional relief would have been warranted, a constitutional decision would have been unnecessary and therefore inappropriate."); *see also Burton v. United States*, 196 U.S. 283, 295 (1905) ("It is not the habit of the court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case.").

B. The Elements And Burden Of Proof In Vaccine Act Cases.

The Vaccine Act provides that a petitioner may receive compensation and other relief under the Vaccine Injury Compensation Program ("Vaccine Program") if injury can be established either by causation in law or causation in fact. Causation in law is established if one of the vaccines listed in the Vaccine Injury Table at 42 U.S.C. § 300aa-14(a) ("Vaccine Table") was administered to a petitioner, and the "first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths" of specific adverse medical conditions associated with the use of each vaccine occurred within a time period specified in the Vaccine Table. *See* 42 U.S.C. § 300aa-14(a). The Vaccine Table is to be read and interpreted by reference to "Qualifications and aids to interpretation," that define the key terms used therein. *Id.* § 300aa-14(b).

Congress also afforded a petitioner the opportunity to receive relief under the Vaccine Program, even if the time period for the first symptom or manifestation of a specified injury is not listed in the Vaccine Table. *See id.* §§ 300aa-11(c)(1)(C)(ii), 300aa-13. Under these circumstances, a petitioner must establish causation in fact, *i.e.*, first, by establishing a *prima facie* case offering evidence of sufficient facts to establish each element of the claim and then by meeting a burden of proof as to each element of the claim by a "preponderance of the evidence" standard. *Id.* § 300aa-13. Accordingly, a non-Vaccine Table petitioner must proffer at least some evidence as to each element of the claim and sufficient evidence to persuade the special master or court by a preponderance of evidence. *Id.*

In interpreting the Vaccine Act, the United States Court of Appeals for the Federal Circuit has held that a petitioner alleging a non-Table vaccine injury must proffer evidence that establishes causation in fact, by a "preponderance of evidence:"

[8] Procedurally, Petitioner was required to raise the issue of constitutionality with the court to preserve the argument on appeal. *See Boggs v. West*, 188 F.3d 1335, 1337–38 (Fed. Cir. 1999) ("As a general rule, an appellate court will not hear on appeal issues that were not clearly raised in the proceedings below.").

> [A] petitioner[] must show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical *or* scientific explanation must support this logical sequence of cause and effect.

Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (internal citations omitted) (emphasis added); *see also Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991) ("[P]etitioner's burden is not to show a generalized 'cause and effect relationship' with listed illnesses, but only to show causation in the particular case. [Otherwise,] . . . a different and greater burden [would be placed] on petitioners than was enacted by Congress.").

In *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006), the United States Court of Appeals for the Federal Circuit re-affirmed the three-part test for determining causation in fact in non-Vaccine Table cases, established in *Althen*, requiring that a petitioner show by preponderant evidence that the vaccination brought about the injury by providing:

> (1) a medical theory causally connecting the vaccination and the injury;
>
> (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
>
> (3) a showing of a proximate temporal relationship between vaccination and injury.

Capizzano, 440 F.3d at 1324 (quoting *Althen*, 418 F.3d at 1278).

If a petitioner is able to establish causation in fact, then the burden of proof shifts to the Government to establish that a factor unrelated to the vaccine was the actual cause of the petitioner's injury. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also Althen*, 418 F.3d at 1278.

C. Petitioner's April 29, 2014 Motion For Review Of The Special Master's April 7, 2014 Decision Denying Entitlement.

1. Petitioner's Argument.

Petitioner's April 29, 2014 Motion For Review ("Pet. Mot.") states six objections to the special master's April 7, 2014 Decision denying entitlement.

First, the special master erred in relying on the testimony and reports of the Government's expert, Dr. Maclaren, an endocrinologist specializing in diabetes, while failing to give sufficient weight to the testimony and reports of Petitioner's expert Dr. Shoenfeld, a leading researcher on autoimmunity. Pet. Mot. 4–6. The special master also mischaracterized this case as principally relating to diabetes, when Petitioner's health problems were caused by an autoimmune response. Pet. Mot. 5. In fact, Dr. Maclaren admitted that his knowledge of autoimmunity is limited to what he learned in medical school. As such, he did not have the

relevant expertise in autoimmune disease. Pet. Mot. 5 (citing 3/30/11 TR 168 (Bercu). If given due weight by the court, Dr. Shoenfeld's opinions provide a theory of causation sufficient to satisfy prong one of the test set forth in *Althen*. *See* 418 F.3d at 1278 (requiring petitioners first to show, by preponderant evidence, "a medical theory causally connecting the vaccination and the injury" to establish causation (quoting *Grant*, 956 F.2d at 1148)).

Second, it was arbitrary and capricious for the special master to conclude that it takes years for symptoms to appear in cases of Type 1 diabetes. Pet. Mot. 6 (citing *Crutchfield*, 2014 WL 1665227, at *10). Petitioner submitted multiple medical articles indicating that a variety of Type 1 diabetes, called fulminant diabetes, is one where the islet cells are destroyed rapidly and symptoms appear within days or weeks of the onset of the autoimmune response. Pet. Mot. 7, 9 (citing Pet. 5/12/11 Arts. 71–74, 78). Although Dr. Maclaren testified that the symptoms of Type 1 diabetes take a long period to manifest, usually years, he was referring to LADA. Pet. Mot. 7.

Third, it was an abuse of discretion for the special master to consider evidence regarding LADA since the medical evidence clearly indicates that Petitioner did not have LADA. Pet. Mot. 11. Specifically, Petitioner submitted medical literature stating that LADA is insulin resistant whereas Petitioner's diabetes has been successfully treated with insulin. Pet. Mot. 7–8, 11. Dr. Maclaren's testimony on this issue was irrelevant, since his opinion concerned a condition that Petitioner does not have. Pet. Mot. 7–8. Therefore, in relying on Dr. Maclaren's testimony to reject the possibility that vaccine exposure triggered rapid-onset fulminant diabetes, the special master acted arbitrarily and capriciously. Pet. Mot. 9. Moreover, it was an abuse of discretion for the special master to admit and consider evidence relating only to LADA, as that evidence is irrelevant in this case. Pet. Mot. 11.

Fourth, the special master's finding that LADA was an alternative theory of causation to the anamnestic response theory described by Dr. Shoenfeld was unlawful, arbitrary, and capricious. Pet. Mot. 12. Since there was no alternative causation theory established for Petitioner's diabetes, it was an abuse of discretion and contrary to 42 U.S.C. § 300aa-13(2)(A) for the special master to attribute Petitioner's diabetes to an unknown event. Pet. Mot. 12.

Fifth, it was arbitrary and capricious for the special master to discount the theories of Dr. Shoenfeld, an expert on autoimmunity, in favor of those of Dr. Maclaren, an endocrinologist. Pet. Mot. 13. Specifically, the special master rejected Dr. Shoenfeld's theory that the rapid onset of Type 1 diabetes in Petitioner was caused by an anamnestic response to her second MMR vaccination. Pet. Mot. 15. Dr. Maclaren is not an expert in immunology and did not proffer any evidence for his conclusion that Petitioner's vaccine did not trigger an anamnestic response against her islet cells. Pet. Mot. 13–14. Therefore, it was an abuse of discretion and arbitrary and capricious for the special master to rely on Dr. Maclaren's testimony in rejecting Petitioner's causation argument. Pet. Mot. 13–14. "[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body*." Pet. Mot. 16 (quoting *Althen*, 418 F.3d at 1280 (emphasis added)). Dr. Shoenfeld articulated a plausible medical theory that Petitioner's diabetes was caused by a rapid autoimmune response to Petitioner's January 26, 2006 MMR vaccination. Pet. Mot. 14–15 (citing 3/30/11 TR 31–34, 47 (Shoenfeld)). Petitioner also submitted medical literature describing the rapid onset of Type 1 diabetes following exposure to a virus, such as

mumps. Pet. Mot. 15 (citing Pet. 5/12/11 Art. 70 at 3 ("Since 1899, there have been many reports of abrupt-onset [Type 1 diabetes] in individuals of all ages within a few days to weeks following mumps infection[.]"); Pet. 5/12/11 Arts. 71–78). This epidemiological data, along with the causation theory expounded by Dr. Shoenfeld, was sufficient to meet the Vaccine Act's preponderance standard as articulated in *Althen*, and it was arbitrary and capricious for the special master to find otherwise. Pet. Mot. 12.

Sixth, it was arbitrary and capricious for the special master to determine that Petitioner's May 13, 2005 blood test was inaccurate. Pet. Mot. 16. This blood test was conducted at NewYork-Presbyterian Hospital seven months before Petitioner received her second MMR vaccine, and the results indicated a normal blood glucose level of 92 mg/dL compared to a reference range of 70–105 mg/dL. Pet. 1/16/09 Ex. 6 at 98. Petitioner argues that the normal results of this blood test refute Dr. Maclaren's theory that Petitioner had LADA and that the destruction of her islet cells had been slowly progressing before receiving the vaccine. Pet. Mot. 16. Yet the special master disregarded the results of this test as inaccurate, based on the testimony of Dr. Maclaren. Pet. Mot. 17 (citing *Crutchfield*, 2014 WL 1665227, at *11 (citing 3/30/11 TR 124–25, 142–43 (Maclaren))). Dr. Maclaren testified that hospital laboratories often mishandle blood samples; specifically, the lab workers do not kill the white blood cells extant in the sample, and these white blood cells continue consuming the glucose before the sample is tested, leading to an artificial drop in blood glucose levels. Pet. Mot. 18 (citing 3/30/11 TR 124 (Maclaren)). Dr. Maclaren, however, proffered no evidence to suggest that the samples were mishandled in this case; in fact, he admitted that he had no knowledge of how Petitioner's blood sample actually was handled. Pet. Mot. 17 (citing 3/30/11 TR 145 (Maclaren)). As such, his testimony on the matter is "not based upon the facts in the record but on altered facts and speculation designed to bolster [a party's] position, [and so] the trial court should exclude it." Pet. Mot. 18–19 (quoting *Guillory v. Domtar Indus. Inc.*, 95 F.3d 1320, 1331 (5th Cir. 1996)). On one hand, medical records "warrant consideration as trustworthy evidence;" on the other, conflicting oral testimony "deserves little weight." Pet. Mot. 17 (quoting *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993)). Moreover, laboratory blood tests are subject to federal regulation and therefore should be considered trustworthy. Pet. Mot. 19 (citing *Consumer Fed'n of Am. v. Dep't of Health & Human Servs.*, 906 F.Supp. 657, 659 (D.D.C. 1995), *rev'd on other grounds*, 83 F.3d 1479 (D.C. Cir. 1996) ("[The Clinical Laboratory Improvement Amendments ("CLIA")] established . . . a comprehensive regulatory system under which hospitals, physicians' offices, and independent laboratory facilities that perform clinical tests are subject to federal oversight and supervision. CLIA requires all clinical laboratories performing tests and examinations on specimens from the human body to obtain certification from HHS.")). Therefore, the special master's decision to disregard Petitioner's May 13, 2005 test results was arbitrary and capricious. Pet. Mot. 19–20.

For these reasons, the special master's April 7, 2014 Decision denying entitlement should be reversed, Petitioner should be awarded compensation, and the case remanded for calculation of damages. Pet. Mot. 20.

2. The Government's Response.

The Government responds that "[a]ll six of petitioner's objections follow from a faulty legal assumption – that the Court of Federal Claims has the ability to review *de novo* the special

master's factual findings and credibility determinations." Gov't Resp. 7. To the contrary, "[if] the special master's conclusion is based on evidence in the record that [is] not wholly implausible, [the United States Court of Federal Claims is] compelled to uphold that finding as not being arbitrary or capricious." Gov't Resp. 6 (quoting *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

Although Petitioner argues that the special master erred in favoring the theories of Dr. Maclaren over those of Dr. Shoenfeld, "credibility determinations are 'virtually unreviewable'" by the United States Court of Federal Claims. Gov't Resp. 8 (quoting *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (quoting *Hambsch v. Dep't of the Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986))). Moreover, although the special master acknowledged Dr. Shoenfeld's considerable expertise in the field of autoimmunity, Dr. Maclaren spent decades studying diabetes specifically, which is the disease from which Petitioner is suffering. Gov't Resp. 8. Dr. Maclaren's exceptional qualifications in the field of Type 1 diabetes made it reasonable for the special master to rely on his testimony with regard to the key finding in the case, *i.e.*, that the process of islet cell destruction in Type 1 diabetes takes a long time, often years, and could not have occurred in the interval between Petitioner's vaccination and the appearance of her symptoms. Gov't Resp. 9. In addition, Dr. Maclaren supported his opinions with medical articles, several of which were cited by the special master in his Decision. Gov't Resp. 9 (citing 8/21/09 Resp. Exs. B, D). Furthermore, Dr. Maclaren's opinion that the blood test performed on Petitioner on May 13, 2005 could have yielded inaccurate results was based on his extensive experience in the field, so that it was not arbitrary and capricious for the special master to accept that opinion. Gov't Resp. 10.

Petitioner misconstrues Dr. Maclaren's testimony on the issue of the timing of islet cell destruction, in arguing that this testimony is applicable only to LADA, a condition that Petitioner does not have. Gov't Resp. 11. In the special master's Decision, however, he indicates that LADA "simply refers to those situations where the first symptoms of diabetes are seen in adulthood." Gov't Resp. 11 (citing *Crutchfield*, 2014 WL 1665227, at *8). Neither of respondent's experts ever suggested that LADA is a separate form of Type 1 diabetes. Gov't Resp. 11. Therefore, Petitioner is wrong to assert that LADA was raised as an "alternative cause," because, in fact, Petitioner never presented a *prima facie* case that the vaccine caused the injury, rendering it unnecessary for the Government to assert an alternative cause. Gov't Resp. 11 n.3. The language quoted by Petitioner from 42 U.S.C. § 300aa-13(a), stating that "factors unrelated to the administration of the vaccine" cannot include any "unexplained, unknown, hypothetical, or undocumentable cause," is relevant only when the Petitioner has presented a *prima facie* case and the burden shifts to the Government to assert an alternative explanation. Gov't Resp. 11 n.3. Because Petitioner failed to present a *prima facie* case, the burden never shifted. Gov't Resp. 11 n.3. Since the Government never had to assert an alternative cause, it was not contrary to law for the special master to deny entitlement, where the cause of the injury is unknown. Gov't Resp. 11.

In addition, the Government argues that the special master correctly rejected Dr. Shoenfeld's opinion. Gov't Resp. 11–12. In particular, Dr. Shoenfeld failed to explain adequately the mechanism by which the MMR vaccination triggered the rapid destruction of islet cells. Gov't Resp. 11. Although Dr. Shoenfeld described how "molecular mimicry," in theory, could cause Petitioner's immune system to attack cells in her body, if they resemble antigens in

the MMR vaccine, he "never explained why he believes that there are molecular 'similarities' between Petitioner's islet cells and any 'particles' in the MMR vaccine." Gov't Resp. 12 (citing *Crutchfield*, 2014 WL 1665227, at *12). Dr. Maclaren testified that he was unaware of any molecular similarities between the islet cells and the components of the MMR vaccine. Gov't Resp. 12 (citing *Crutchfield*, 2014 WL 1665227, at *13). Likewise, Dr. Bercu found no evidence that molecular mimicry contributed to the onset of Petitioner's Type 1 diabetes. Gov't Resp. 12. Therefore, it was not arbitrary and capricious nor an abuse of discretion for the special master to favor the opinions of the Government's experts over those of Dr. Shoenfeld. Gov't Resp. 12.

The Government also argues that it was appropriate for the special master to consider epidemiological evidence in this case. Gov't Resp. 12–13. The United States Court of Appeals for the Federal Circuit has held that special masters may take into account epidemiological evidence in "reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." Gov't Resp. 13 (quoting *Andreu v. Sec'y Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)). Therefore, it was appropriate for the special master to consider the medical literature presented, including the IOM Report. Gov't 1/31/12 Art. NNN. As the special master noted, the court often has relied on the findings of the Institute of Medicine and the 2012 Report in particular addressed the exact issue under consideration in this case, *i.e.*, whether there is any evidence that the MMR vaccine can cause Type 1 diabetes. Gov't Resp. 13–14 (citing *Crutchfield*, 2014 WL 1665227, at *15–16). The Report found no association between MMR vaccination and Type 1 diabetes, so the special master did not err in relying upon these studies to reject the opinions of Dr. Shoenfeld. Gov't Resp. 14.

Finally, Dr. Shoenfeld's testimony was internally inconsistent and unpersuasive. Gov't Resp. 14. For example, he suggested that adjuvants in the MMR vaccine could contribute to the rapid onset of diabetes, but later conceded that the MMR vaccine does not, in fact, contain adjuvants. Gov't Resp. 14 (citing *Crutchfield*, 2014 WL 1665227, at *18). Therefore it was not arbitrary and capricious for the special master to find this testimony unpersuasive. Gov't Resp. 14.

In sum, Petitioner failed to show by preponderant evidence a causation theory that met the *Althen* elements: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Gov't Resp. 14–15 (quoting *Althen*, 418 F.3d at 1278). Therefore, the court should deny Petitioner's motion for review. Gov't Resp. 16.

3. The Court's Resolution.

Petitioner has presented evidence that, as a general proposition, molecular mimicry could explain how a vaccine *could* trigger an autoimmune disorder, such as Type 1 diabetes. 3/30/11 TR 32–33 (Shoenfeld) (discussing molecular mimicry and the rubella virus); *see Althen*, 418 F.3d at 1278 (requiring that a petitioner show "a medical theory causally connecting the vaccination and the injury"); *see also Pafford v. Health & Human Servs.*, 451 F.3d 1352, 1356 (Fed. Cir. 2006) (asking, under the first *Althen* element, "can [the] vaccine(s) at issue cause the type of injury alleged?" (internal quotation omitted)). Even if Dr. Shoenfeld's testimony

satisfied the first prong of *Althen*, under the very deferential standard of review afforded the decision of the special master, it was not arbitrary and capricious for him to find Dr. Maclaren's testimony more credible than that of Dr. Shoenfeld, and thereby give substantial weight to Dr. Maclaren's rejection of a causal link between the MMR vaccine and Petitioner's Type 1 diabetes. *See Lampe*, 219 F.3d at 1360 (holding that the United States Court of Federal Claims may not "reweigh the factual evidence" (quoting *Munn*, 970 F.2d at 871)); *see also Crutchfield*, 2014 WL 1665227, at *10 ("[T]here were many flaws in Dr. Shoenfeld's testimony, which made his opinion unpersuasive in general"); *Crutchfield*, 2014 WL 1665227, at *22 n.25 (noting that other Vaccine Act cases have criticized and rejected Dr. Shoenfeld's theories).

The second element of causation that must be satisfied is "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d 1278 (internal quotation omitted). It is true that Dr. Shoenfeld presented evidence that Type 1 diabetes does not always take years for symptoms to manifest, contrary to the special master's finding. *Compare* Pet. 5/12/11 Arts. 70–80 (discussing rapid-onset diabetes and its relationship to vaccines) *and* 3/30/11 TR 179–82 (Shoenfeld) (identifying articles that refute the idea that Type 1 diabetes is always slowly progressing), *with Crutchfield*, 2014 WL 1665227, at *10 (finding, as "most persuasive," that symptoms of Type 1 diabetes "takes a lengthy period, usually *years*," to develop (emphasis in original)). And, the special master may have been mistaken in concluding that Type 1 diabetes *always* takes years for the symptoms to manifest. Pet. 5/12/11 Arts. 70–80. But, as the special master found, Dr. Shoenfeld failed to explain how molecular mimicry would operate in Petitioner's case, because he did not explain why there were similarities between islet cells and parts of the MMR vaccine. *Crutchfield*, 2014 WL 1665227, at *12 (citing 3/30/11 TR 32 (Shoenfeld)). Instead, Dr. Shoenfeld posited that, as a general proposition, molecular mimicry *could* explain how a vaccine *could* trigger an autoimmune disorder, but he did not explain how it *did so* in this case.

In addition, the epidemiological evidence weighs heavily against finding that the MMR vaccine causes Type 1 diabetes; the IOM Report is nearly dispositive on this point. Gov't 1/31/12 Art. NNN at 9. Petitioner's discussion of LADA is misguided; none of the experts ever recognized LADA as a separate disease or testified that it must *always* be insulin resistant. The special master supported his decisions with relevant evidence and addressed the major points of Dr. Shoenfeld's testimony, ultimately before finding his testimony of less value. *See Crutchfield*, 2014 WL 1665227, at *11–13, *15, *18–19; *see also id.* at *11 (describing Dr. Shoenfeld's testimony as "poorly explained, flawed, and unpersuasive on its face"). As such, the second element of *Althen* was not established. *See Pafford*, 451 F.3d at 1355–56.

Finally, the special master found that Petitioner did not satisfy the third element of *Althen*, because the onset of symptoms only one to two months after vaccination "militates strongly *against* [the] Petition on the timeliness issue, since the evidence strongly indicates that *whatever* caused the Type 1 diabetes, it would take a *year or more* for the islet cell destruction to proliferate to the point where symptoms would develop." *Crutchfield*, 2014 WL 1665227, at *22 (emphases in original); *see also Althen*, 418 F.3d at 1278 (requiring "a proximate temporal relationship between vaccination and injury"). Petitioner also may be correct that the special master should not have disregarded the results of the blood test prior to her vaccination, particularly since they were not definitive. Petitioner may be correct that Dr. Maclaren proffered no evidence indicating that the blood sample was mishandled, so that the "normal" results of

Petitioner's blood test evidenced that Petitioner did not have LADA prior to the vaccination. Pet. Mot. 16; 3/30/11 TR 145 (Maclaren). Nevertheless, Dr. Maclaren's unrefuted testimony indicates that a more accurate test for identifying cell destruction—a hemoglobin A1c test—was not conducted at that time and when that test was later administered, the results indicated a high level of islet cell destruction that would necessarily have begun prior to vaccination. *See Crutchfield*, 2014 WL 1665227, at *11; 3/30/11 TR 125–26 (Maclaren).

Therefore, the special master correctly found that Petitioner did not establish causation in this case.

IV. CONCLUSION.

For these reasons, the April 7, 2014 Decision of the special master is affirmed.

IT IS SO ORDERED.

s/ Susan G. Braden
SUSAN G. BRADEN
Judge